EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BEST MEDICAL INTERNATIONAL, INC., Plaintiff, v. VARIAN MEDICAL SYSTEMS, INC., AND VARIAN MEDICAL SYSTEMS INTERNATIONAL AG, Defendants.	C.A. No.: 18-1599-MN

DEFENDANTS' PRELIMINARY INVALIDITY CONTENTIONS

I. PRELIMINARY STATEMENT

Defendants Varian Medical Systems, Inc. and Varian Medical Systems International AG (collectively, "Varian") hereby provide their Preliminary Invalidity Contentions with respect to U.S. Patent Nos. 6,038,283 ("the '283 patent"), 6,393,096 ("the '096 patent"), 7,266,175 ("the '175 patent") and 7,015,490 ("the '490 patent") (collectively, "the Asserted Patents") per the Court's July 15, 2019 Scheduling Order (D.I. 29) and August 14, 2019 Stipulation and Order Extending Time (D.I. 38).

Varian's Contentions address and respond to only the claims from the Asserted Patents that Plaintiff Best Medical International, Inc. ("BMI") asserts in this case ("the Asserted Claims") and should not be deemed to suggest that any non-asserted claims of the Asserted Patents are valid or enforceable. As of the date of these Contentions, BMI has asserted the following claims under 35 U.S.C. §§ 217(a)-(c):

- Claims 6, 7, 9, 10, 12, 22–28, 34, 42, and 46 of the '283 patent
- Claims 18, 21, 23, 31–33, 36, 40, and 43–46 of the '096 patent
- Claims 13–16, and 19 of the '175 patent
- Claims 1, 4, and 17–19 of the '490 patent

Varian's investigation and analysis of the Asserted Patents and the prior art remain ongoing, and the Contentions herein are based on information currently available to Varian. Additionally, Varian notes that BMI's August 30, 2019 Preliminary Infringement Contentions are incomplete, inadequate, and unclear, because *inter alia* they fail to identify specifically where each limitation of each Asserted Claim is found within each accused instrumentality. BMI, therefore, has not provided Varian with the requisite disclosures showing how it is interpreting the Asserted Claims for Varian to prepare its disclosure of Preliminary Invalidity Contentions. Varian also has not yet obtained requisite discovery from BMI or third parties, including the named inventors or the prosecuting attorneys of the Asserted Patents, prior-art authors, and manufacturers of prior art systems. For these reasons, additional information regarding certain defenses, including, for example, knowledge or use by others under § 102(a), public use or on sale bar under § 102(b), and prior or different inventorship under § 102(f), may become available later in the case, including via discovery that Varian has been trying to obtain and that BMI has been delaying. Varian reserves all rights to supplement or otherwise modify these contentions based on developments in this case including ongoing prior art searches, continuing discovery, claim construction, evaluation of the scope and content of the prior art, changes in BMI's Asserted Claims or Infringement Contentions, changes in the applicable law, or for any other reason permitted by applicable law and the Court's rulings.

In addition, until such time as the Court provides its claim-construction rulings, Varian cannot be certain that its Contentions incorporate the Court's claim interpretations. To the extent that the Contentions herein reflect consistency with any construction adopted by BMI, no inference is intended nor should any be drawn that Varian agrees with BMI's claim constructions, and Varian expressly reserves its right to contest such constructions. Further, no inference is intended nor should any be drawn that any Asserted Claim satisfies 35 U.S.C. § 112, and Varian reserves the right to contend that they do not (as detailed below). With respect to secondary indicia of non-obviousness pertinent to the asserted patents, Varian reserves all rights to assert any such points or respond to any advanced by BMI as the case proceeds.

In the claim charts attached to these preliminary invalidity contentions, citations are made to exemplary passages in the prior art. Varian reserves the right to rely upon additional passages that also may be applicable, or that may become applicable in light of any developments on claim construction, changes in Plaintiff's infringement contentions, and/or information obtained during remaining discovery. Similarly, the obviousness combinations of prior art under 35 U.S.C. § 103 that Varian provides herein are exemplary and not intended to be exhaustive. Numerous additional obviousness combinations of the prior art are possible, and Varian reserves the right to use any such combination in this litigation, including in expert reports.

II. IDENTIFICATION OF PRIOR ART

Varian lists below each item of prior art that anticipates and/or renders obvious one or more of the Asserted Claims. The list below also includes documents that Varian may use as background art to discuss the technology at issue, and/or to illustrate the state of the art at the time of the alleged inventions. Varian reserves the right to rely upon additional prior art that may be uncovered during continuing investigation and discovery.

Patents and Patent Applications	**Filing Dates**
JP Patent No. 2551734 to Chiaki Kato ("Kato")	Nov. 6, 1996
US Patent App. Pub. 2003/0086530 to Karl Otto ("Otto")	Sept. 25, 2001
US Patent No. 5,458,125 to Achim Schweikard ("Schweikard")	Jan. 28, 1994
US Patent No. 5,647,663 to Timothy Holmes ("Holmes")	Jan. 5, 1996
US Patent No. 6,661,871 to Ramon Siochi ("Siochi")	Sept. 28, 2001
US Patent No. 6,853,705 to Sha Chang ("Chang")	Mar. 28, 2003
US Patent No. 7,162,008 to Matt Earl, et al. ("Earl")	Dec. 3, 2001
Other Printed Publications	**Publication Dates**
M. Alber, et al., *Intensity Modulated Photon Beams Subject to a Minimal Surface Smoothing Constraint*, 45 Phys. Med. Biol. N49 ("Alber 2000")	2000

M. Alber, et al., *Optimization of Intensity Modulated Radiotherapy Under Constraints for Static and Dynamic MLC Delivery*, 46 Phys. Med. Biol. 3229 (Alber 2001)	Nov. 14, 2001
M. Alber, et al., *Hyperion – An Integrated IMRT Planning Tool*, ICCR 2000 ("Alber Hyperion 2000")	2000
A. Bel, et al., *Target Margins For Random Geometrical Treatment Uncertainties in Conformal Radiotherapy*, 23 Med. Phys. 1537 ("Bel")	Sept. 1996
Mark P. Carol, et al., *The Field-Matching Problem as it Applies to the Peacock Three Dimensional Conformal System for Intensity Modulation*, 34 Int. J. Radiation Biol. Phys. 183 ("Carol 1996")	1996
Mark P. Carol, *Integrated 3-D Conformal Multivane Intensity Modulation Delivery System for Radiotherapy*, Proceedings of the XIth Int. Conference on the Use of Conformal Therapy on Mar. 20-24th, 172 ("Carol 1994 Art. 1")	Mar. 1994
Mark P. Carol, et al., *An Automatic 3-D Conformal Treatment Planning System for Linear Accelerator Based Beam Modulation Radiotherapy*, Proceedings of the XIth Int. Conference on the Use of Conformal Therapy on Mar. 20-24th, 108 ("Carol 1994 Art. 2")	Mar. 1994
Mark P. Carol, *Peacock™: A System for Planning and Rotational Delivery of Intensity-Modulated Fields*, 6 Int. J. Imaging Sys. and Tech. 56 ("Carol 1995")	1995
Jianrong Dai, et al., *Minimizing the Number of Segments in a Delivery Sequence for Intensity-Modulated Radiation Therapy with a Multileaf Collimator*, 28 Med. Phys. 2113 ("Dai")	Oct. 2001
Michael Goitein, *The Comparison of Treatment Plans*, 2 Seminars in Radiation Oncology 245 ("Goitein")	Oct. 1992
Per Hahn, et al., *Treatment Planning for Protocol-Based Radiation Therapy*, 18 Int. J. Radiation Oncology Biol. Phys. 937 ("Hahn")	1990
Carine Kulik, et al., *Conformal Radiotherapy Optimization With Micromultileaf Collimators: Comparison With Radiosurgery Techniques*, 53 Int. J. Radiation Oncology Biol. Phys. 1038 ("Kulik")	2002
Mark Langer, et al., *Optimization of Beam Weights Under Dose-Volume Restrictions*, 13 Int. J. Radiation Oncology Biol. Phys. 1255 ("Langer 1987")	1987
Mark Langer, et al., *The Reliability of Optimization Under Dose-Volume Limits*, 26 Int. J. Radiation Oncology Biol. Phys. 529 ("Langer 1993")	1993

Mark Langer, et al., *Improved Leaf Sequencing Reduces Segments or Monitor Units Needed to Deliver IMRT Using Multileaf Collimators*, 28 Med. Phys. 2450 ("Langer 2001")	Dec. 2001
W. Laub, et al., *Intensity Modulated Radiation Therapy (IMRT) in the Radiotherapy Treatment of Colo-Rectal Cancer: the Influence of Profile Smoothing on the Efficiency of Delivery*, 2 J. Radiotherapy in Practice 189 ("Laub")	2002
Theodore Lawrence, et al., *An Application of Dose Volume Histograms to the Treatment of Intrahepatic Malignancies With Radiation Therapy*, 19 Int. J. Radiation Oncology Biol. Phys. 1041 ("Lawrence")	1990
Bengt Lind, et al., *Development of Treatment Techniques for Radiotherapy Optimization*, 6 Int. J. Imaging Sys. and Tech. 33 ("Lind")	1995
John T. Lyman, *Complication Probability as Assessed from Dose-Volume Histograms*, 104 Radiation Research S-13 ("Lyman 1985")	Nov. 1985
John T. Lyman, et al., *Optimization of Radiation Therapy, IV: A Dose-Volume Histogram Reduction Algorithm*, 17 Int. J. Radiation Oncology Biol. Phys. 433 ("Lyman 1989")	1989
Lijun Ma, et al., *Synchronizing Dynamic Multileaf Collimators for Producing Two-Dimensional Intensity-Modulated Fields With Minimum Beam Delivery Time*, 44 Int. J. Radiation Oncology Biol. Phys. 1147 ("Ma")	1999
Radhe Mohan, et al., *The Potential and Limitations of the Inverse Radiotherapy Technique*, 32 Radiotherapy and Oncology 232 ("Mohan 1994")	1994
Radhe Mohan, et al., *The Impact of Fluctuations in Intensity Patterns on the Number of Monitor Units and the Quality and Accuracy of Intensity Modulated Radiotherapy*, 27 Med. Phys. 1226 ("Mohan 2000")	June 2000
Radhe Mohan, et al., *Clinically Relevant Optimization of 3-D Conformal Treatments*, 19 Med. Phys. 933 ("Mohan 1992")	Jul. / Aug. 1992
Steven Morrill, et al., *Constrained Simulated Annealing for Optimized Radiation Therapy Treatment Planning*, 33 Computer Methods and Programs in Biomedicine 135 ("Morrill 1990")	1990
Steven Morrill, et al., *Dose-Volume Considerations With Linear Programming Optimization*, 18 Med. Phys. 1201 ("Morrill 1991 Art. 1")	Nov. / Dec. 1991

Steven Morrill, et al., *Treatment Planning Optimization Using Constrained Simulated Annealing*, 36 Phys. Med. Biol. 1341 ("Morrill 1991 Art. 2")	1991
Steven Morrill, et al., *Very Fast Simulated Reannealing in Radiation Therapy Treatment Plan Optimization*, 31 Int. J. Radiation Oncology Biol. Phys. 179 ("Morrill 1994")	1994
Anthony Neal, et al., *Comparison of Treatment Techniques For Conformal Therapy of the Prostate Using Dose-Volume Histograms and Normal Tissue Complication Probabilities*, 37 Radiotherapy and Oncology 29 ("Neal")	1995
Andrezj Niemierko, et al., *Optimization of 3D Radiation Therapy With Both Physical and Biological End Points and Constraints*, 23 Int. J. Radiation Oncology Biol. Phys. 99 ("Niemierko 1992 Art. 1")	1992
Andrzej Niemierko, et al., *Random Search Algorithm (RONSC) for Optimization of Radiation Therapy With Both Physical and Biological End Points and Constraints* 23 Int. J. Radiation Oncology Biol. Phys. 89 ("Niemierko 1992 Art. 2")	1992
Mark Oldham, et al., *A Comparison of Conventional 'Forward Planning' With Inverse Planning for 3D Conformal Radiotherapy of the Prostate*, 35 Radiotherapy and Oncology 248 ("Oldham 1995 Art. 1")	1995
Mark Oldham, et al., *The Optimization and Inherent Limitations of 3D Conformal Radiotherapy Treatment Plans of the Prostate*, 68 British J. of Radiology 882 ("Oldham 1995 Art. 2")	Aug. 1995
K. Otto et al., *Enhancing IMRT with MLC Rotation*, 2002 AAPM Annual Meeting Program, TU-C-517A-1029, 29 Med. Phys. 1305-06 ("Otto Abstract 2002")	June 2002
Karl Otto, et al., *Enhancement of IMRT Delivery Through MLC Rotation*, 47 Phys. Med. Biol. 3997 ("Otto 2002")	2002
Christopher Raphael, *Mathematical Modeling of Objectives in Radiation Therapy Treatment Planning*, 37 Phys. Med. Biol. 1293 ("Raphael")	1992
Isaac Rosen, et al., *Comparison of Simulated Annealing Algorithms for Conformal Therapy Treatment Planning*, 33 Int. J. Radiation Oncology Bio. Phys. 1091 ("Rosen")	1995
Shlomo Shalev, et al., *The Objective Evaluation of Alternative Treatment Plans: I. Images of Regret*, 15 Int. J. Radiation Oncology 763 ("Shalev 1988")	Apr. 1, 1988

Shlomo Shalev, et al., *The Objective Evaluation of Alternative Treatment Plans: II. Score Functions*, 20 Int. J. Radiation Oncology Bio. Phys. 1067 ("Shalev 1991")	1991
Jeffrey V. Siebers, et al., *Incorporating Multi-Leaf Collimator Leaf Sequencing into Iterative IMRT Optimization*, 29 Med. Phys. 952 ("Siebers")	June 2002
Spiridon V. Spirou, et al., *Smoothing Intensity-Modulated Beam Profiles to Improve the Efficiency of Delivery*, 28 Med. Phys. 2105 ("Spirou")	Oct. 2001
Edward S. Sternick, *The Theory & Practice of Intensity Modulated Radiation Therapy* ("Sternick")	1997
William Que, *Comparison of Algorithms For Multileaf Collimator Field Segmentation*, 26 Med. Phys. 2390 ("Que")	Nov. 1999
J. Tervo, et al., *A Model for the Control of a Multileaf Collimator in Radiation Therapy Treatment Planning*, 16 Inverse Problems 1875 ("Tervo")	2000
Arie Van't Riet, *A Conformation Number to Quantify the Degree of Conformality in Brachytherapy and External Beam Irradiation: Application to the Prostate*, 37 Int. J. Radiation Oncology 731 ("Van't Riet")	1997
David A. Viggars, et al., *The Objective Evaluation of Alternative Treatment Plans III: The Quantitative Analysis of Dose Volume Histograms*, 23 Int. J. Radiation Oncology Biol. Phys. 419 ("Viggars")	1992
Steve Webb, *Optimization of Conformal Radiotherapy Dose Distributions by Simulated Annealing*, 34 Phys. Med. Biol. 1349 ("Webb 1989")	1989
Steve Webb, *Optimization by Simulated Annealing of Three-Dimensional Conformal Treatment Planning for Radiation Fields Defined by a Multileaf Collimator*, 36 Phys. Med. Biol. 1201 ("Webb 1991")	1991
Steve Webb, *Optimized Three-Dimensional Treatment Planning for Volumes With Concave Outlines Using a Multileaf Collimator*, Advanced Radiation Therapy Tumor Response Monitoring and Treatment Planning 495 ("Webb 1992")	1992
Steve Webb, *The Physics of Three-Dimensional Radiation Therapy: Conformal Radiotherapy, Radiosurgery, and Treatment Planning*, Ch. 2 ("Webb 1993")	1993

Steve Webb, *Optimizing the Planning of Intensity-Modulated Radiotherapy*, 39 Phys. Med. Biol. 2229 ("Webb 1994")	1994
Steve Webb, *Optimizing Radiation Therapy Inverse Treatment Planning Using the Simulated Annealing Technique*, 6 Int. J. Imaging Sys. and Tech. 71 ("Webb 1995")	1995
Steve Webb, *A Simple Method to Control Aspects of Fluence Modulation in IMRT Planning*, 46 Phys. Med. Biol. N187 ("Webb 2001")	2001
Shiao Woo, et al. *A Comparison of Intensity Modulated Conformal Therapy With a Conventional External Beam Stereotactic Radiosurgery System for the Treatment of Single and Multiple Intracranial Lesions*, 35 Int. J. Radiation Oncology Biol. Phys. 593 ("Woo")	1996
Andrew Wu, et al., *Evaluation of Dose Calculation Algorithm of the Peacock System for Multileaf Intensity Modulation Collimator*, 36 Int. J. Radiation Oncology Biol. Phys. 1225 ("Wu")	1996
Ping Xia, et al., *Multileaf Collimator Leaf Sequencing Algorithm for Intensity Modulated Beams With Multiple Static Segments*, 25 Med. Phys. 1424 ("Xia")	Aug. 1998

In addition, Varian is currently investigating whether the following prior-art systems/products embodied some or all of the Asserted Claims before the applicable priority dates:

Prior-Art Systems Known, Used, Sold, or Offered for Sale
CMS FOCUS
CORVUS Inverse Treatment Planning System which may also include: • PEACOCK Plan • MIMiC Mulitleaf Collimator • Crane
COVIRA Algorithm
Helax TMS IMRT
iSis3D Treatment Planning System
KONRAD Inverse Treatment Planning System
Langer Optimization Program implemented at Massachusetts General Hospital
Mageras and Mohan Algorithm, implemented at Memorial Sloan-Kettering Cancer Center
Medical College of Virginia IMRT System

Niemierko Optimization Program implemented at Massachusetts General Hospital
Nucletron PLATO
OSCAR
PEACOCK Intensity Modulated Radiation Therapy System which may also include: • PEACOCK Plan • MIMiC Multileaf Collimator
PEACOCK Plan
Philips ADAC PINNACLE (including Version 3 and Version 4.2k)
PLAN 3D
PlanUNC ("PLUNC")
Radionics Software Application X-Knife II (RSA) System
Siemens IMART
Siemens IMFAST
Siemens PRIMART
Siemens Primus
Simulated Annealing Implementation of VOXELPLAN (integrated into VIRTUOS) implemented at the Institute of Cancer Research Royal Marsden Hospital
Spirou Algorithms, implemented at Memorial Sloan-Kettering Cancer Center
Stryker Leibinger VIRTUOSO
UCSFMLC
UMPLAN
Varian CADPLAN
Varian 2100C
Varian 2100EX

Varian intends to seek third-party discovery from third parties for information regarding prior-art systems/products, including but not limited to the following third parties:

Ann Arbor, University of Michigan Dep't of Radiation Oncology
BrainLab AG
Direx Medical Systems
DKFZ (German Cancer Research Center) Heidelberg

Elekta AB
Harvard Medical School
IBA Dosimetry America (formerly Scanditronix Wellhöfer North America)
IBM UK Scientific Research Centre at Hursley
Institute Curie (L'Institut Curie)
Philips Medical Systems, Inc.
Manitoba Cancer Treatment and Research Foundation
Massachusetts General Hospital
MDS Nordion AB (formerly Helax AB Corp.)
Memorial Sloan-Kettering Cancer Center
MRC Systems GMBH
Netherlands Cancer Institute (NKI)
Sherouse Systems, Inc.
Siemens Medical Solutions USA, Inc. (Siemens Healthineers AG)
Stryker Leibinger
The Institute of Cancer Research Royal Marsden Hospital
University of California San Francisco Department of Radiation Oncology
University of North Carolina School of Medicine, Department of Radiation Oncology
University of Texas Medical Branch, Dep't of Radiation Therapy
Virginia Commonwealth University Medical Center, Massey Cancer Center

Finally, Varian is investigating and is seeking discovery from BMI regarding knowledge or use by others under § 102(a), public use or on-sale bar under § 102(b), derivation or prior inventorship under §§ 102(f)/(g), and the identity of persons or entities involved in and the circumstances surrounding the making of the claimed invention before BMI. Varian reserves all rights to rely on conception and reduction to practice documents produced (or to be produced) by BMI, including but not limited to BESTV00000715–0834, and source code to be produced by BMI (including source code referenced in the above documents), for such evidence.

III. ANTICIPATION AND OBVIOUSNESS UNDER 35 U.S.C. §§ 102-103

The following sections and exhibits hereto set forth Varian's preliminary invalidity contentions for the Asserted Patent based on the prior art known and available to Varian thus far. To the extent any limitation is deemed not to be met exactly by an item of prior art, Varian contends

that the difference would have been obvious to a person of ordinary skill in the art and within the knowledge of one skilled in the art at the time of the alleged invention, so that the claimed invention would have been obvious both in light of the single reference alone and/or in light of combined references.

As a general matter, all portions of each prior art item are relied upon to support the disclosure of each patent claim limitation, as all portions provide general support. Supporting citations are nevertheless provided, but do not necessarily represent every location where a particular claim term may be found in the prior art item. Varian reserves the right to rely on additional, or different, portions of the prior art items other than those specifically cited in the attached claims charts, and to supplement and/or amend these charts.

In addition to the exemplary prior art items and teachings identified in these preliminary invalidity contentions, the common knowledge of those of ordinary skill in the art also constitutes prior art, and may be relied on by Varian through testimony or declarations in combination with the identified prior art. The knowledge of a person of ordinary skill in the art at the time of the alleged invention would also include, for example, the known advantages and disadvantages of each of the limitations recited in the Asserted Claims. It would have been obvious to combine the references and teachings identified herein with one another, based on the nature of the problem to be solved, the general knowledge of a person of ordinary skill in the art, the teachings of other art in existence at that time, and the recognition of similarities between the art and the claimed features. On these bases, each identified prior art item can be combined with the others if a particular prior-art item lacks or does not disclose a limitation or feature of an asserted claim.

More particularly, and without limitation, all of the following recognized rationales support a finding of obviousness:

- Combining prior art elements according to known methods to yield predictable results;
- Simple substitution of one known element for another to obtain predictable results;
- Use of known techniques to improve similar devices, methods, or products in the same way;

- Applying a known technique to a known device, method, or product ready for improvement to yield predictable results;
- ‘‘Obvious to try’’—i.e., choosing from a finite number of known, predictable solutions, with a reasonable expectation of success;
- Known work in one field of endeavor prompting variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; and
- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art items or to combine prior art teachings to arrive at the claimed invention.

The rationales identified above would have motivated a person of skill in the art to combine the above-identified prior art items and teachings. As the Supreme Court held in *KSR International Co. v. Teleflex, Inc.*, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." 550 U.S. 398, 416 (2007). The Supreme Court further held that, "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id*. at 418.

Moreover, the Supreme Court held that "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id*. at 420. Indeed, the Supreme Court held that it is sufficient that a combination of elements was "obvious to try," holding that, "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *Id*.

Patents like the ones asserted here are invalid, the Supreme Court explained, because "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility." *Id*. at 1741. Here, each of the prior art items identified above is directed to the same field as that of the asserted patents. Further, each prior-art item was directed to the same problem or problems that the Asserted Patents purportedly solved. The Asserted Claims therefore represent—at the very most—mere "ordinary skill and common sense," not innovation. Stated differently, the alleged inventions are, at most, obvious combinations or adaptations of well-known technology used in predicable ways.

To the extent that the prior art cited herein reflects knowledge, use, and/or sale or offer for sale under the provisions of § 102, Varian reserves all rights to contend that the Asserted Claims of one or more Asserted Patents are invalid because the alleged invention was known or used by others under § 102(a), or publicly used or on sale pursuant to § 102(b), before the relevant priority date. For example, Nomos itself had products on sale more than one year prior to the provisional applications of the '096, '175, and '490 patents. These products include the CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan; the MIMiC Mulitleaf Collimator; the Crane; etc. (*See, e.g.*, *https://web.archive.org/web/19970212065923/http:/www.nomos.com:80/fprod.html*.) As described on NOMOS's prior website:

> CORVUS uses a fast simulated annealing algorithm, controlled by cost functions, to arrive at a set of delivery parameters which will approach an optimal plan. The optimal plan or goal is specified in a clinically intuitive manner through the use of partial volume data and desired CDVH curves input by the user.

https://web.archive.org/web/19970528021418fw_/http://www.nomos.com/dcorvus.html.

Varian's investigation and analysis remain ongoing, and BMI has yet to produce any documents regarding the prior knowledge, use, and sale of the alleged inventions, despite the Court's order to the contrary (*see* D.I. 50). Varian reserves its right to modify, amend and/or further supplement these contentions as information becomes available, and as discovery proceeds.

In addition, Varian reserves all rights to contend that the Asserted Claims of one or more Asserted Patents are invalid, under 35 U.S.C. § 102(f), for failure to name the proper inventors, once BMI provides the relevant discovery regarding the conception and reduction to practice of the Asserted Claims, and depositions of the named inventors are completed.

Varian further intends to file and serve on BMI petitions for *inter partes* review ("IPR") of the '283, '096, '175, and '490 patents by October 18, 2019. Varian incorporates those IPR petitions herein by reference. The IPR petitions provide a detailed discussion of each challenged patent, the prosecution history, and an overview of the primary prior art references, and a limitation-by-limitation invalidity analysis for all Asserted Claims. Varian also incorporates its related identification of exhibits to the IPRs, which include some of the prior art listed herein and expert declarations, and further incorporates by reference as additional prior art each and every reference cited in and considered during prosecution of the asserted patents.

A. '283 Patent

Varian contends that the Asserted Claims of the '283 patent are anticipated by the prior art, or obvious in view of the prior art, as described in the table below. Varian attaches hereto Exhibits A-1 through A-18, which contain claim charts demonstrating the invalidity of the Asserted Claims of the '283 patent. Varian also incorporates by reference in its entirety any future filings for IPR on the '283 patent, which may further set forth the bases for invalidity of the '283 Asserted Claims.

'283 Patent	**Application of Prior Art and Prior Art Combinations**
Asserted claims 6, 7, 9, 10, 12, 22-28, 34, 42, 46	Each asserted claim is anticipated and/or obvious in light of the following prior art: • Morrill 1991 Art. 2 • Morrill 1991 Art. 2 in view of Viggars • Morrill 1991 Art. 2 in view of Viggars and Schweikard • Morrill 1990 in view of Viggars • Morrill 1990 in view of Viggars and Schweikard • Carol 1995 in view of Viggars • Carol 1995 in view of Viggars and Schweikard • Neal in view of Viggars • Neal in view of Viggars and Schweikard

	• Oldham 1995 Art. 1 in view of Viggars • Oldham 1995 Art. 1 in view of Viggars and Schweikard • Oldham 1995 Art. 2 in view of Viggars • Oldham 1995 Art. 2 in view of Viggars and Schweikard • Carol 1994 Art. 2 in view of Viggars • Carol 1994 Art. 2 in view of Viggars and Schweikard • Carol 1994 Art. 1 in view of Viggars • Carol 1994 Art. 1 in view of Viggars and Schweikard • Mohan 1992 in view of Viggars • Mohan 1992 in view of Viggars and Schweikard • Mohan 1994 in view of Viggars • Mohan 1994 in view of Viggars and Schweikard • Rosen in view of Viggars • Rosen in view of Viggars and Schweikard • Webb 1989 in view of Viggars • Webb 1989 in view of Viggars and Schweikard • Webb 1991 in view of Viggars • Webb 1991 in view of Viggars and Schweikard • Webb 1995 in view of Viggars • Webb 1995 in view of Viggars and Schweikard • Carol 1995 in view of Morrill 1991 Art. 1 • Carol 1995 in view of Morrill 1991 Art. 1 and Schweikard • Oldham 1995 Art. 1 in view of Morrill 1991 Art. 1 • Oldham 1995 Art. 1 in view of Morrill 1991 Art. 1 and Schweikard • Neal in view of Morrill 1991 Art. 1 • Neal in view of Morrill 1991 Art. 1 and Schweikard • Morrill 1990 in view of Morrill 1991 Art. 1 • Morrill 1990 in view of Morrill 1991 Art. 1 and Schweikard • Morrill 1991 Art. 2 in view of Morrill 1991 Art. 1 • Morrill 1991 Art. 2 in view of Morrill 1991 Art. 1 and Schweikard • Carol 1995 in view of Hahn • Carol 1995 in view of Hahn and Schweikard • Oldham 1995 Art. 1 in view of Hahn • Oldham 1995 Art. 1 in view of Hahn and Schweikard • Neal in view of Hahn • Neal in view of Hahn and Schweikard • Morrill 1990 in view of Hahn • Morrill 1990 in view of Hahn and Schweikard • Morrill 1991 in view of Hahn • Morrill 1991 in view of Hahn and Schweikard • PEACOCK Plan in view of Viggars

	• PEACOCK Plan in view of Viggars and Schweikard • PEACOCK Plan in view of Morrill 1991 Art. 2

B. '096 Patent

Varian contends that the Asserted Claims of the '096 patent are anticipated by the prior art, or obvious in view of the prior art, as described in the table below. Varian attaches hereto Exhibits B-1 through B-15, which contain claim charts demonstrating the invalidity of the Asserted Claims of the '096 patent. Varian also incorporates by reference in its entirety any future filings for IPR on the '096 patent, which may further set forth the bases for invalidity of the '096 Asserted Claims.

'096 Patent	**Application of Prior Art and Prior Art Combinations**
Asserted claims 18, 21, 23, 31-33, 36, 40, 43-46	Each asserted claim is anticipated and/or obvious in light of the following prior art: • Carol 1995 in view of Viggars • Carol 1995 in view of Viggars and Shalev 1991 • Carol 1995 in view of Viggars and Bel • Carol 1995 in view of Sternick • Carol 1995 in view of Viggars and Sternick • Carol 1995 in view of Viggars and Woo • Carol 1996 in view of Viggars • Carol 1996 in view of Viggars and Shalev 1991 • Carol 1996 in view of Viggars and Bel • Carol 1996 in view of Viggars and Woo • Carol 1996 in view of Sternick • Carol 1996 in view of Viggars and Sternick • Sternick in view of Shalev 1991 • Sternick in view of Bel • Sternick in view of Woo • Oldham 1995 Art. 1 in view of Viggars • Oldham 1995 Art. 1 in view of Viggars and Woo • Oldham 1995 Art. 1 in view of Viggars and Morrill 1990 • Oldham 1995 Art. 1 in view of Viggars and Shalev 1991 • Oldham 1995 Art. 1 in view of Viggars and Bel • Oldham 1995 Art. 2 in view of Viggars • Oldham 1995 Art. 2 in view of Viggars and Woo • Oldham 1995 Art. 2 in view of Viggars and Morrill 1990 • Oldham 1995 Art. 2 in view of Viggars and Shalev 1991 • Oldham 1995 Art. 2 in view of Viggars and Bel • Holmes in view of Viggars

	• Holmes in view of Viggars and Shalev 1991 • Holmes in view of Viggars and Bel • Holmes in view of Viggars and Woo • Morrill 1991 Art. 2 in view of Viggars • Morrill 1991 Art. 2 in view of Viggars and Shalev 1991 • Morrill 1991 Art. 2 in view of Viggars and Bel • Morrill 1990 in view of Viggars • Morrill 1990 in view of Viggars and Woo • Morrill 1990 in view of Viggars and Shalev 1991 • Morrill 1990 in view of Viggars and Bel • Webb 1995 in view of Viggars • Webb 1995 in view of Viggars and Shalev 1991 • Webb 1995 in view of Viggars and Bel • Webb 1995 in view of Viggars and Woo • CORVUS Inverse Treatment Planning System • CORVUS Inverse Treatment Planning System in view of Woo • CORVUS Inverse Treatment Planning System in view of Sternick • CORVUS Inverse Treatment Planning System in view of Sternick and Woo • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Woo • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Sternick and Woo • CORVUS Inverse Treatment Planning System incorporating PEACOCK plan in view of Carol 1995 and Woo • Peacock Intensity Modulated Radiation Therapy System in view of Viggars • Peacock Intensity Modulated Radiation Therapy System in view of Viggars and Woo • Peacock Intensity Modulated Radiation Therapy System in view of Sternick • Peacock Intensity Modulated Radiation Therapy System in view of Viggars and Sternick

C. ’175 Patent

Varian contends that the Asserted Claims of the ’175 patent are anticipated by the prior art, or obvious in view of the prior art, as described in the table below. Varian attaches hereto Exhibits C-1 through C-15, which contain claim charts demonstrating the invalidity of the Asserted Claims of the ’175 patent. Varian also incorporates by reference in its entirety any future filings for IPR on the ’175 patent, which may further set forth the bases for invalidity of the ’175 Asserted Claims.

'175 Patent	**Application of Prior Art and Prior Art Combinations**
Asserted claims 13–16, 19	Each asserted claim is anticipated and/or obvious in light of the following prior art: • Earl in view of Alber 2000 • Laub in view of Alber 2000 • Philips ADAC Pinnacle Version 4.2f in view of Laub and Alber 2000 • Elekta linear accelerator with Philips ADAC Pinnacle Version 4.2f in view of Laub and Alber 2000 • Spirou • Spirou in view of Siebers • Spirou in view of Langer 2001 and Siebers • Spirou in view of Dai and Siebers • Spirou in view of Ma and Siebers • Spirou in view of Xia and Siebers • Spirou in view of Siochi and Siebers • Spirou in view of Que and Siebers • Spirou in view of Earl • Spirou in view of Tervo and Siebers • Spirou Algorithms in view of Spirou • Spirou Algorithms in view of Spirou, Langer 2001, and Siebers • Spirou Algorithms in view of Spirou, Dai, and Siebers • Spirou Algorithms in view of Spirou, Ma, and Siebers • Spirou Algorithms in view of Spirou, Xia, and Siebers • Spirou Algorithms in view of Spirou, Siochi, and Siebers • Spirou Algorithms in view of Spirou, Que, and Siebers • Spirou Algorithms in view of Spirou and Earl • Medical College of Virginia IMRT System in view of Spirou, Dai, and Siebers • Medical College of Virginia IMRT System in view of Spirou, Ma, and Siebers • Medical College of Virginia IMRT System in view of Spirou, Xia, and Siebers • Medical College of Virginia IMRT System in view of Spirou, Siochi, and Siebers • Medical College of Virginia IMRT System in view of Spirou, Que, and Siebers • UCSFMLC in view of Spirou, Xia, and Siebers • Webb 2001 • Webb 2001 in view of Dai and Siebers • Webb 2001 in view of Langer 2001 and Siebers

	• Webb 2001 in view of Ma and Siebers • Webb 2001 in view of Xia and Siebers • Webb 2001 in view of Siochi and Siebers • Webb 2001 in view of Tervo and Siebers • Webb 2001 in view of Que and Siebers • Webb 2001 in view of Earl, Webb 1993, and Mohan • Medical College of Virginia IMRT System in view of Webb 2001, Dai, and Siebers • Medical College of Virginia IMRT System in view of Webb 2001, Ma, and Siebers • Medical College of Virginia IMRT System in view of Webb 2001, Xia, and Siebers • Medical College of Virginia IMRT System in view of Webb 2001, Siochi, and Siebers • Medical College of Virginia IMRT System in view of Webb 2001, Que, and Siebers • UCSFMLC in view of Webb 2001, Xia, and Siebers • Webb 2001 in view of Earl, Webb 1993, and Mohan 2000 • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Earl and Alber 2000 • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Laub and Alber 2000 • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Spirou • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Spirou and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Spirou, Langer 2001, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Spirou, Dai, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Spirou, Ma, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Spirou, Xia, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Spirou, Siochi, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Spirou, Que, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Spirou and Earl • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Spirou, Tervo, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Webb 2001

	• CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Webb 2001, Dai, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Webb 2001, Langer 2001, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Webb 2001, Ma ,and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Webb 2001, Xia, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Webb 2001, Siochi ,and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Webb 2001, Que ,and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Webb 2001, Tervo, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan in view of Webb 2001, Earl, Webb 1993, and Mohan

D. ’490 Patent

Varian contends that the Asserted Claims of the ’490 patent are anticipated by the prior art, or obvious in view of the prior art, as described in the table below. Varian attaches hereto Exhibits D-1 through D-15, which contain claim charts demonstrating the invalidity of the Asserted Claims of the ’490 patent. Varian also incorporates by reference in its entirety any future filings for IPR on the ’490 patent, which may further set forth the bases for invalidity of the ’490 Asserted Claims.

’490 Patent	**Application of Prior Art and Prior Art Combinations**
Asserted claims 1, 4, 17–19	Each asserted claim is anticipated and/or obvious in light of the following prior art: • Otto in view of Chang, Webb 1993, and Mohan 2000 • Otto in view of Siebers • Otto in view of Spirou, Otto Abstract 2002, and Langer 2001 • Otto in view of Spirou in further view of Langer and Tervo • Otto in view of Xia in further view of Siebers • Otto in view of Siochi in further view of Siebers • Otto in view of Dai in further view of Siebers • Otto in view of Que and Siebers • Kulik in view of Chang, Webb 1993, and Mohan 2000 • Kulik in view of Siebers • Kulik in view of Spirou, Otto AAPM 2002, and Langer 2001

	• Kulik in view of Xia in further view of Siebers • Kulik in view of Siochi in further view of Siebers • Kulik in view of Dai in further view of Siebers • Kulik in view of Que and Siebers • Otto 2002 in view of Otto Abstract 2002, Webb 2001, and Spirou • Spirou Algorithms in view of Otto, Spirou, Otto Abstract 2002, and Langer 2001 • Spirou Algorithms in view of Kulik, Spirou, Otto AAPM 2002, and Langer 2001 • Medical College of Virginia IMRT System in view of Otto and Siebers • Medical College of Virginia IMRT System in view of Otto, Xia, and Siebers • Medical College of Virginia IMRT System in view of Otto, Siochi, and Siebers • Medical College of Virginia IMRT System in view of Otto, Dai, and Siebers • Medical College of Virginia IMRT System in view of Kulik and Siebers • Medical College of Virginia IMRT System in view of Kulik, Xia, and Siebers • Medical College of Virginia IMRT System in view of Kulik, Siochi, and Siebers • Medical College of Virginia IMRT System in view of Kulik, Dai, and Siebers • UCSFMLC in view of Otto, Xia, and Siebers • UCSFMLC in view of Kulik, Xia, and Siebers • UCSFMLC in view of Otto, Siochi, and Siebers • UCSFMLC in view of Kulik, Dai, and Siebers • UCSFMLC in view of Otto, Que, and Siebers • UCSFMLC in view of Kulik, Que, and Siebers • PlanUNC in view of Otto, Chang, Webb 1993, and Mohan 2000 • PlanUNC in view of Kulik, Chang, Webb 1993, and Mohan 2000 • Varian 2100C with Standard MLC in view of Otto, Chang, Webb 1993, and Mohan 2000 • Varian 2100C with Standard MLC in view of Otto, Que, and Siebers • Varian 2100C with Standard MLC in view of Kulik, Que, and Siebers • Varian 2100EX with Millennium MLC in view of Otto, Chang, Webb 1993, and Mohan 2000

	• Varian 2100EX with Millennium MLC in view of Otto, Que, and Siebers • Varian 2100EX with Millennium MLC in view of Kulik, Que, and Siebers • Varian 2100C with Standard MLC in view of Otto and Siebers • Varian 2100EX with Millennium MLC in view of Otto and Siebers • Varian 2100C with Standard MLC in view of Otto, Spirou, Otto Abstract 2002, and Langer 2001 • Varian 2100EX with Millennium MLC in view of Otto, Spirou, Otto Abstract 2002, and Langer 2001 • Varian 2100C with Standard MLC in view of Otto, Xia, and Siebers • Varian 2100EX with Millennium MLC in view of Otto, Xia, and Siebers • Varian 2100C with Standard MLC in view of Otto, Siochi, and Siebers • Varian 2100EX with Millennium MLC in view of Otto, Siochi, and Siebers • Varian 2100C with Standard MLC in view of Otto, Dai, and Siebers • Varian 2100EX with Millennium MLC in view of Otto, Dai, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Otto, Chang, Webb 1993, and Mohan 2000 • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Otto and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Otto, Spirou, Otto Abstract 2002, and Langer 2001 • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Otto, Xia, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Otto, Siochi, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Otto, Dai, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Otto, Que, and Siebers

	• CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Kulik, Que, and Siebers • Varian 2100C with Standard MLC in view of Kulik, Chang, Webb 1993, and Mohan 2000 • Varian 2100EX with Millennium MLC in view of Kulik, Chang, Webb 1993, and Mohan 2000 • Varian 2100C with Standard MLC in view of Kulik and Siebers • Varian 2100EX with Millennium MLC in view of Kulik and Siebers • Varian 2100C with Standard MLC in view of Kulik, Spirou, Otto AAPM 2002, and Langer 2001 • Varian 2100EX with Millennium MLC in view of Kulik, Spirou, Otto AAPM 2002, and Langer 2001 • Varian 2100C with Standard MLC in view of Kulik, Xia, and Siebers • Varian 2100EX with Millennium MLC in view of Kulik, Xia, and Siebers • Varian 2100C with Standard MLC in view of Kulik, Siochi, and Siebers • Varian 2100EX with Millennium MLC in view of Kulik, Siochi, and Siebers • Varian 2100C with Standard MLC in view of Kulik, Dai, and Siebers • Varian 2100EX with Millennium MLC in view of Kulik, Dai, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Kulik, Chang, Webb 1993, and Mohan 2000 • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Kulik and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Kulik, Spirou, Otto AAPM 2002, and Langer 2001 • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Kulik, Xia, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Kulik, Siochi, and Siebers • CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator in view of Kulik, Dai, and Siebers

IV. OTHER INVALIDITY DEFENSES

A. '283 and '096 Patents

1. Invalidity Under 35 U.S.C. § 101

The Asserted Claims of the '283 and '096 patents are invalid under § 101 because they are directed to patent-ineligible concepts. The limitations of each of the Asserted Claims, considered individually and as an ordered combination, add nothing to transform the nature of the claim into a patent-eligible application (*e.g.*, they only recite abstract ideas, insignificant post-solution activity, and/or conventional and obvious steps or generic components) and fail to provide an inventive concept to confer patentability. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014); *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016).

For example, the Asserted Claims of the '283 and '096 patents are directed to mathematical algorithms, which the Federal Circuit has long considered patent-ineligible abstract mental processes. In addition, the Asserted Claims recite results (*e.g.*, optimal beam arrangement) without adequately defining specific ways of achieving them, and thus purport to encompass entire classes of solutions, rather than a particular solution.

Moreover, by the '283 and '096 patents' own admissions, the Asserted Claims recite generic and "conventional" components and routine functions to implement their claimed mathematical algorithms. *See, e.g.*, '283 patent at 3:17–26, 9:53–54, 9:59–64, 13:33–37. The use of such algorithms in conformal radiation therapy merely applies the abstract idea to a technological environment and does not otherwise shift the "focus" of the abstract claims to something more concrete. There is also nothing about the order or combination of limitations in the Asserted Claims that is inventive or unconventional. Indeed, the '283 and '096 patents admit that the claimed algorithms follow the same conventional sequences and combinations of elements already recognized in the prior art. *See, e.g.*, '283 patent at 12:13–45. Thus, the Asserted Claims of the '283 and '096 patents are not directed to patent-eligible subject matter and are invalid under § 101.

The foregoing points are merely exemplary and are not exhaustive reasons for why the Asserted Claims of the '283 and '096 patents are invalid under § 101.

2. Invalidity Under 35 U.S.C. § 112

a. Indefiniteness

Various asserted claims of the '283 and '096 patents are invalid for indefiniteness under § 112 because they fail to inform, with any reasonable certainty or objective boundaries, those skilled in the art about the scope of the claimed inventions. *See Nautilus v. Biosig Instruments, Inc.*, 134 S. Ct. 2140 (2014). On this basis, and by way of example without limitation, Varian contends that at least the following claim terms of the '283 and '096 patents fail to satisfy the definiteness requirement under § 112 and accordingly render their corresponding claims (in parentheses) invalid:

- "[pre-determined] desired dose prescription" ('283 claims 7, 9, 10, 12, 22–28, 34; '096 claims 18, 21, 31, 36, 40, 43–46)
- "acceptable level" ('283 claim 14)
- "change the proposed radiation beam arrangement" ('283 claims 5–10, 12, 22–28; '096 claims 18, 31, 36)
- "biologically uniform" and "biologically polymorphic" ('283 claim 34; '096 claim 45)
- "range of values to indicate the importance of objects to be irradiated" ('096 claim 43)
- "range of conformality control factors" ('096 claim 43)
- "exceed the cost function by a set amount" ('096 claims 31–33)

In addition, Varian contends that the term "using different cost function parameters depending on the target or structure type" ('096 claim 46) is already inherent in claim 43 (from which claim 46 depends). Claim 46 therefore does not specify a further limitation of the subject matter claimed compared to claim 43 as required by § 112 and is invalid on that basis. To the

extent that claim 46 is read to further limit claim 43, one of ordinary skill in the art would not be able to discern the scope of claim 46 with any reasonable certainty or objective boundaries, and thus claim 46 (and/or claim 25) is invalid for indefiniteness under § 112.

Varian further contends that the term "dose distribution" ('096 claim 18, which depends on claim 1) is indefinite for lack of antecedent basis.

Varian's analysis is continuing and the parties have not yet exchanged terms to be construed. Varian reserves the right to amend these preliminary invalidity contentions to identify additional indefinite claims in a manner consistent with the Court's rulings on claim construction and its operative scheduling order.

b. Lack of Written Description

Various asserted claims of the '283 and '096 patents are invalid for lack of written description support under § 112 because the specification fails to adequately describe the claimed invention such that one skilled in the art would conclude that the inventor had possession of the claimed invention at the time of filing. *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1344–45 (Fed. Cir. 2005). By way of example, and without limitation, Varian contends that at least the following claims of the '283 and '096 patents are invalid for failing to satisfy the written description requirement under § 112:

- '096 claims 31–33 are invalid for lack of written description support because the patent specification provides no disclosure or any other support for the claim language "exceed the cost function by a set amount." The specification only describes exceeding a radiation limit, *see, e.g.*, '096 patent at 12:28–13:6, and not exceeding a cost function. Thus, in addition to not being able to discern the scope of this claim language with any reasonable certainty or objective boundaries as discussed above, one of skill in the art also would not have concluded that the named inventors of the '096 patent had possession of an invention in which the cost function is exceeded by a set amount as claimed.

Varian's analysis is continuing, and Varian reserves the right to supplement or otherwise amend these preliminary invalidity contentions to identify additional claims that lack adequate written description support in light of further developments in this case including claim construction and discovery.

c. Lack of Enablement

Various asserted claims of the '283 and '096 patents are invalid for lack of enablement under § 112 because the specification does not contain sufficient information to enable a person of ordinary skill in the art to make and use the claimed invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). By way of example, and without limitation, Varian contends that at least the following claim terms of the '283 and '096 patents fail to satisfy the enablement requirement under § 112:

- '096 claims 31–33 are invalid for lack of enablement. As discussed above, the patent specification provides no disclosure or any other support for the claim language "exceed the cost function by a set amount." In addition to this claim language being indefinite and lacking adequate written description support as discussed above, one of skill in the art would not have been able to practice the full scope of the claimed invention without undue experimentation.
- '283 claims 6, 7, 9, 20, 21, 27, 34, 42, 46 and '096 claims 33, 36, 40, 44 are also invalid for lack of enablement. In particular, the patent specification provides no detail or other support for "applying the optimized radiation beam arrangement to the patient with a conformal radiation therapy apparatus" as claimed. Instead, the patent specification focuses almost entirely on treatment planning makes only glancing reference to how to apply or implement such a treatment plan using conformal radiation therapy apparatuses, *see, e.g.*, '283 at 5:46–47, 6:16-17, 7:1–5, 7:26–30, 8:14–16, 16:22–25; '096 patent at 16:34–37, without disclosing any specifics regarding how to do so. In light of the deficiencies in the patent

specification, one of skill in the art further would not have been able to practice the full scope of the claimed invention without undue experimentation.

Varian's analysis is continuing, and Varian reserves the right to supplement or otherwise amend these preliminary invalidity contentions to identify additional claims that fail the enablement requirement in light of further developments in this case including claim construction and discovery.

3. Double Patenting

Asserted claims 18, 21, 23, 31–33, 36, 40 of the '096 patent are further invalid for statutory and/or obviousness-type double patenting compared to claims of the '283 patent.

B. '175 Patent

1. Invalidity Under 35 U.S.C. § 101

The Asserted Claims of the '175 patent are ineligible under § 101 because they are directed to patent-ineligible concepts, and the limitations of each of the Asserted Claims, considered individually and as an ordered combination, add nothing to transform the nature of the claim into a patent-eligible application and fail to provide an inventive concept to confer patentability. *Alice*, 573 U.S. at 217.

For example, the Asserted Claims are directed to nothing more than controlling tradeoffs between efficiency and quality when optimizing a radiation treatment plan. Evaluating tradeoffs between quality and efficiency is a fundamental activity that humans have been performing for years. Moreover, evaluating a cost function according to cost terms is simply a mathematical algorithm and, as such, it is an unpatentable "mental process." In addition, evaluating intensity maps according to cost functions is mere data collection and analysis, which the Federal Circuit has repeatedly found abstract. Finally, the Asserted Claims of the '175 patent contain no inventive concept whatsoever. None of the individual elements of the asserted claims is inventive—instead, they recite generic, black-box computing functions (*e.g.*, "assigning," "evaluating," "rejecting"), conventional and generic components (*e.g.*, an "optimizer"), and basic computing concepts. And

the '175 patent specification and file history make clear that the two key variables/considerations in the claims—dose distribution and treatment efficiency—were well-known in the prior art. *See, e.g.*, '175 patent at 1:13–32; '175 File History (May 3, 2006 Office Action; Aug. 7, 2006 Applicant Arguments). And the ordered combination of steps is neither inventive nor unconventional, as—for example—it is routine to assign a cost term before evaluating a cost function. *See, e.g.*,'175 File History (Aug. 7, 2006 Applicant Arguments) ("A cost function may, for example, have several terms where each term is designed to meet some high-level goal.") Thus, the Asserted Claims of the '175 patent are not directed to patent-eligible subject matter and are invalid under § 101.

The foregoing points are merely exemplary and are not exhaustive reasons for why the Asserted Claims of the '175 patent are invalid under § 101.

2. Invalidity Under 35 U.S.C. § 112

a. Indefiniteness

By way of example, and without limitation, Varian contends that at least the following claim terms of the '175 patent fail to satisfy the definiteness requirement under § 112(b):

- "delivery efficiency" ('175 claims 13, 19)
- "delivery cost" ('175 claims 13–16, 19)
- "assigning a delivery cost term … based on complexity of each respective intensity map" ('175 claims 13)
- "intensity map" ('175, claims 13–16, 19)
- "within an optimizer" ('175 claims 13, 19)
- "rejecting each intensity map resulting in the delivery cost term exceeding a preselected threshold value" ('175 claim 19)
- "a function of delivery time" ('175 claim 14)

Varian's analysis is continuing and the parties have not yet exchanged terms to be construed. Varian reserves the right to amend these preliminary invalidity contentions to identify

additional indefinite claims in a manner consistent with the Court's rulings on claim construction and its operative scheduling order.

b. Lack of Written Description

By way of example, and without limitation, Varian contends that at least the following claims of the '175 patent are invalid for failing to satisfy the written description requirement under § 112:

- To the extent BMI alleges that the terms "complexity," "delivery efficiency," and "delivery cost," and/or "cost function" in the '175 claims 13–16, and 19, cover subject matter not explicitly disclosed in the '175 specification, those claims are invalid for lack of written description support because the specification provides no disclosure or any other support for such interpretations of those claim terms.
- The '175 specification does not provide written description support for "evaluating an objective cost function for each of the plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the dosimetric cost term representing dosimetric fitness of the respective intensity map and the delivery cost term representing delivery efficiency" as recited in claim 13. For example, the '175 specification does not disclose any objective cost function that includes both a dosimetric cost term and a delivery cost term.
- The '175 specification does not provide written description support for "evaluating an objective cost function within an optimizer for each of a plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the delivery cost term representing total monitor units to deliver radiation according to a beam arrangement represented by the respective intensity map" as recited in claim 19. For example, the '175 specification does not disclose any objective cost function that includes both a dosimetric cost term and a delivery cost term representing total monitor units.

- To the extent BMI alleges that the asserted '175 claims cover more methods than the "three methods" disclosed in the '175 specification, *see, e.g.*, '175 patent at 2:46–3:19, the asserted claims are invalid for lack of written description support because the specification provides no disclosure or any other support for any methods beyond those three.
- To the extent BMI alleges that "a function of delivery time required to deliver radiation" covers anything beyond total monitor units or segment count, *see, e.g.*, '175 patent at 2:23–39, '175 claim 14 is invalid for lack of written description support because the specification provides no disclosure or any other support for anything else that is "proportional to" treatment time.
- To the extent BMI alleges that "the assignment based on complexity of each respective intensity map" in '175 claim 16 covers assignments beyond those disclosed in the '175 specification, *see, e.g.*, '175 patent at 2:52–55, '175 claim 16 is invalid for lack of written description support because the specification provides no disclosure or any other support for any other assignments.
- To the extent BMI proposes that "intensity map" is a representation of a single beam, the '175 specification does not disclose the use of a "dosimetric cost term representing dosimetric fitness," as recited in claim 13, of a single-beam representation.
- To the extent BMI proposes that "intensity map" is a representation of a single beam, the '175 specification does not disclose the use of a "dosimetric cost term," as recited in claim 19, of a single-beam representation.

Varian's analysis is continuing, and Varian reserves the right to supplement or otherwise amend these preliminary invalidity contentions to identify additional claims that lack adequate written description support in light of further developments in this case including claim construction and discovery.

c. Lack of Enablement

By way of example, and without limitation, Varian contends that at least the following claim terms of the '175 patent fail to satisfy the enablement requirement under § 112:

- Varian incorporates its indefiniteness and lack of written description disclosures for the '175 patent. In addition to the asserted '175 claims being indefinite and/or lacking adequate written description support as discussed above, one of skill in the art would not have been able to practice the full scope of the claimed invention in the '175 asserted claims without undue experimentation.
- The '175 specification does not fully enable a person of ordinary skill in the art with respect to "evaluating an objective cost function for each of the plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the dosimetric cost term representing dosimetric fitness of the respective intensity map and the delivery cost term representing delivery efficiency" as recited in claim 13. For example, the '175 specification does not disclose any objective cost function that includes both a dosimetric cost term and a delivery cost term, let alone enable a person of ordinary skill in the art with respect to "evaluating an objective cost function for each of the plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the dosimetric cost term representing dosimetric fitness of the respective intensity map and the delivery cost term representing delivery efficiency."
- The '175 specification does not fully enable a person of ordinary skill in the art with respect to "evaluating an objective cost function within an optimizer for each of a plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the delivery cost term representing total monitor units to deliver radiation according to a beam arrangement represented by the respective intensity map" as recited in claim 19. For example, the '175 specification does not disclose, let alone enable, any objective cost function that

includes both a dosimetric cost term and a delivery cost term representing total monitor units, , let alone enable a person of ordinary skill in the art with respect to "evaluating an objective cost function within an optimizer for each of a plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the delivery cost term representing total monitor units to deliver radiation according to a beam arrangement represented by the respective intensity map."

- To the extent BMI proposes that "intensity map" is a representation of a single beam, the '175 specification does not enable a person of ordinary skill in the art with respect to the use of a "dosimetric cost term representing dosimetric fitness," as recited in claim 13, of a single-beam representation.
- To the extent BMI proposes that "intensity map" is a representation of a single beam, the '175 specification does not enable a person of ordinary skill in the art with respect to the use of a "dosimetric cost term," as recited in claim 19, of a single-beam representation.

Varian's analysis is continuing, and Varian reserves the right to supplement or otherwise amend these preliminary invalidity contentions to identify additional claims that fail the enablement requirement in light of further developments in this case including claim construction and discovery.

C. '490 Patent

1. Invalidity Under 35 U.S.C. § 101

The Asserted Claims of the '490 patent are ineligible under § 101 because they are directed to patent-ineligible concepts, and the limitations of each of the Asserted Claims, considered individually and as an ordered combination, add nothing to transform the nature of the claim into a patent-eligible application and fail to provide an inventive concept to confer patentability. *Alice*, 573 U.S. at 217.

For example, the '490 patent specification concedes that its only alleged improvement over the prior art is "a new algorithm to determine collimator angles in favoring, or enhancing, IMRT radiation therapy treatment plan efficiency." *See, e.g.*, '490 patent at 2:1–4. This is confirmed by the fact that the '490 patent is based on an article by the named inventors entitled "A New Algorithm for Determining Collimator Angles that Favor Efficiency in MLC based IMRT Delivery." *See, e.g.*, '490 patent ("Other Publications"). Mathematical algorithms are abstract "mental processes" and claims directed to them—including the '490 patent Asserted Claims—are patent ineligible under § 101. Moreover, the '490 patent concedes that the "new algorithm" does not need to be implemented using a computer, but if it was, it would be implemented using "conventional" components. *See, e.g.*, '490 patent at 2:28, 6:4–12, 6:62–67. The application of this algorithm to the field of radiation therapy does not make the claim any less abstract. Moreover, just as with the '175 patent, evaluating tradeoffs between quality and efficiency is a fundamental activity that humans have been performing for years, which underscores the abstract, patent-ineligible nature of the '490 Asserted Claims.

The Asserted Claims of the '490 patent also contain no inventive concept. None of the individual elements of the claims is inventive, as the '490 patent specification and file history make clear that the claimed multi-leaf collimator components were conventional and existed in the prior art, and the "new algorithm" is processed on a conventional computer. *See, e.g.*, '490 patent at 6:4–12, 6:62–67. In addition, the ordered combination of steps is neither inventive nor unconventional, as—for example—it is routine to assign a cost term before evaluating a cost function. For at least these reasons, the Asserted Claims of the '490 patent are not directed to patent-eligible subject matter and are invalid under § 101.

The foregoing points are merely exemplary and are not exhaustive reasons for why the Asserted Claims of the '490 patent are invalid under § 101.

2. Invalidity Under 35 U.S.C. § 112

a. Indefiniteness

By way of example, and without limitation, Varian contends that at least the following claim terms of the '490 patent fail to satisfy the definiteness requirement under § 112(b):

- "calculating an initial radiation beam arrangement according to a desired prescription" ('490 claim 1)
- "changing the radiation beam arrangement by incorporating a first cost function to determine the collimator" ('490 claim 1)
- "enhance delivery efficiency by reducing a number of radiation beam segments and reducing a number of radiation beam monitor units" ('490 claim 1)
- "enhance delivery efficiency by reducing a number of radiation beam segments and reducing a number of radiation beam monitor units" ('490 claims 1, 17)
- "significantly leads to a lesser correspondence" ('490 claim 4)
- "significantly less correspondence" ('490 claim 4)
- "maximum effective length" ('490 claim 18)

Varian's analysis is continuing and the parties have not yet exchanged terms to be construed. Varian reserves the right to amend these preliminary invalidity contentions to identify additional indefinite claims in a manner consistent with the Court's rulings on claim construction and its operative scheduling order.

b. Lack of Written Description

By way of example, and without limitation, Varian contends that at least the following claims of the '490 patent are invalid for failing to satisfy the written description requirement under § 112:

- The purported invention of the '490 patent is a "a method and apparatus for determining the collimator angle ***before optimization*** in an inverse treatment planning system which favors, or enhances, the delivery efficiency by reducing the number of segments and MUs." *See, e.g.*, '490 patent at 1:57–61 (emphasis added);

see also id. at 1:51–56, 3:11–14 ("[T]his function leads to the identification of the collimator angle best suited for application to the treatment plan prior to treatment plan optimization."). To the extent BMI alleges that the Asserted Claims of the '490 patent encompass any functionality during or after treatment plan optimization, or any optimization that is not used to determine a collimator angle prior to treatment plan optimization, those claims are invalid for lack of written description support because the specification provides no disclosure or any other support for such functionality.

Varian's analysis is continuing, and Varian reserves the right to supplement or otherwise amend these preliminary invalidity contentions to identify additional claims that lack adequate written description support in light of further developments in this case including claim construction and discovery.

c. Lack of Enablement

By way of example, and without limitation, Varian contends that at least the following claim terms of the '490 patent fail to satisfy the enablement requirement under § 112:

- To the extent BMI alleges that the Asserted Claims of the '490 patent encompass any functionality during or after treatment plan optimization, or any functionality not used to determine a collimator angle prior to treatment plan optimization, those claims are invalid for lack of enablement because one of skill in the art would not have been able to practice the full scope of the claimed invention in the '490 Asserted Claims without undue experimentation.
- Varian also incorporates its indefiniteness disclosures for the '490 patent. In addition to the asserted '490 claims being indefinite, one of skill in the art would not have been able to practice the full scope of the claimed invention in the '490 asserted claims without undue experimentation.

Varian's analysis is continuing, and Varian reserves the right to supplement or otherwise amend these preliminary invalidity contentions to identify additional claims that fail the enablement requirement in light of further developments in this case including claim construction and discovery.

Respectfully submitted,

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APPENDIX A

The following chart lists each item of prior art that Varian has currently identified as anticipating and/or rendering obvious one or more of the Asserted Claims, as well as Asserted Patent(s) to which they correspond. Varian's investigation is ongoing, and Varian reserves the right to assert any item of prior art listed in Section II against any of the Asserted Patents, whether or not included in this list below.

Prior Art Reference	Patent the Prior Art Applies To
Alber 2000	'175 patent
Alber 2001	'175 patent
Alber Hyperion 2000	'175 patent
Bel	'096 patent
Carol 1994 Art. 1	'096 patent, '283 patent
Carol 1994 Art. 2	'096 patent, '283 patent
Carol 1995	'096 patent, '283 patent
Carol 1996	'096 patent, '283 patent
Chang	'490 patent
CORVUS Inverse Treatment Planning System	'096 patent
CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan	'096 patent, '175 patent
CORVUS Inverse Treatment Planning System incorporating PEACOCK Plan with MIMiC Multileaf Collimator	'490 patent
Dai	'175 patent, '490 patent
Earl	'175 patent
Elekta linear accelerator with Philips ADAC Pinnacle Version 4.2f	'175 patent
Goitein	'096 patent, '283 patent
Hahn	'283 patent
Holmes	'096 patent, '283 patent
Kato	'096 patent, '283 patent
Kulik	'175 patent, '490 patent
Langer 1987	'096 patent, '283 patent
Langer 1993	'096 patent, '283 patent

Prior Art Reference	Patent the Prior Art Applies To
Langer 2001	’175 patent, ’490 patent
Laub	’175 patent
Lawrence	’096 patent, ’283 patent
Lind	’096 patent, ’283 patent
Lyman 1985	’096 patent, ’283 patent
Lyman 1989	’096 patent, ’283 patent
Ma	’175 patent
Medical College of Virginia IMRT System	’175 patent, ’490 patent
Mohan 1992	’096 patent, ’283 patent
Mohan 1994	’096 patent, ’283 patent
Mohan 2000	’175 patent, ’490 patent
Morrill 1990	’096 patent, ’283 patent
Morrill 1991 Art. 1	’096 patent, ’283 patent
Morrill 1991 Art. 2	’096 patent, ’283 patent
Morrill 1994	’096 patent, ’283 patent
Neal	’096 patent, ’283 patent
Niemierko 1992 Art. 1	’096 patent, ’283 patent
Niemierko 1992 Art. 2	’096 patent, ’283 patent
Oldham 1995 Art. 1	’096 patent, ’283 patent
Oldham 1995 Art. 2	’096 patent, ’283 patent
Otto	’490 patent
Otto 2002	’490 patent
Otto Abstract 2002	’490 patent
Peacock Intensity Modulated Radiation Therapy System	’096 patent
PEACOCK Plan	’096 patent, ’283 patent
Philips ADAC Pinnacle Version 4.2f	’175 patent
PlanUNC	’490 patent
Que	’175 patent, ’490 patent
Raphael	’096 patent, ’283 patent
Rosen	’096 patent, ’283 patent
Schweikard	’283 patent
Shalev 1988	’096 patent
Shalev 1991	’096 patent
Siebers	’175 patent, ’490 patent

Prior Art Reference	Patent the Prior Art Applies To
Siochi	’175 patent, ’490 patent
Spirou	’175 patent, ’490 patent
Spirou Algorithms	’175 patent, ’490 patent
Sternick	’096 patent
Tervo	’175 patent, ’490 patent
UCSFMLC	’175 patent, ’490 patent
Van’t Riet	’096 patent, ’283 patent
Varian 2100C with Standard MLC	’490 patent
Varian 2100EX with Millennium MLC	’490 patent
Viggars	’096 patent, ’283 patent
Webb 1989	’283 patent
Webb 1991	’283 patent
Webb 1992	’096 patent, ’283 patent
Webb 1993	’175 patent, ’490 patent
Webb 1994	’096 patent, ’283 patent
Webb 1995	’096 patent, ’283 patent
Webb 2001	’175 patent
Woo	’096 patent, ’283 patent
Wu	’096 patent, ’283 patent
Xia	’175 patent, ’490 patent

CERTIFICATE OF SERVICE

I, Kristen E. Lovin, hereby certify that on October 15, 2019, this document was served on the persons listed below in the manner indicated:

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